

CLINDAMYCIN PHOSPHATE- clindamycin phosphate solution
Cadila Healthcare Limited

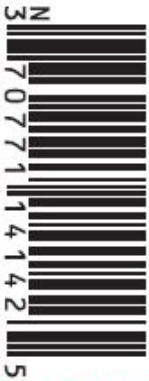
Clindamycin Phosphate Topical Solution USP, 1%

PACKAGE LABEL-PRINCIPAL DISPLAY PANEL

NDC 70771-1414-2

Clindamycin phosphate topical solution USP, 1%

Rx only




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70771
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NDC 70771-1414-2

**Clindamycin
Phosphate
Topical
Solution,
USP**

1 %*

Solution for topical use only

 **zydus**
pharmaceuticals

30 mL
Rx only

*Each mL contains clindamycin phosphate equivalent to 10mg/mL (1%) of clindamycin. Also contains isopropyl alcohol, 50%; propylene glycol and purified water. Sodium hydroxide or hydrochloric acid may be added to adjust pH between 4.0 to 7.0.

DOSAGE AND USE: See accompanying prescribing information.

Store at 20° to 25°C (68° to 77°F) [See USP Controlled Room Temperature]. Protect from freezing. Store in an upright fashion.

Keep container tightly closed.

For external use only. Avoid contact with eyes.

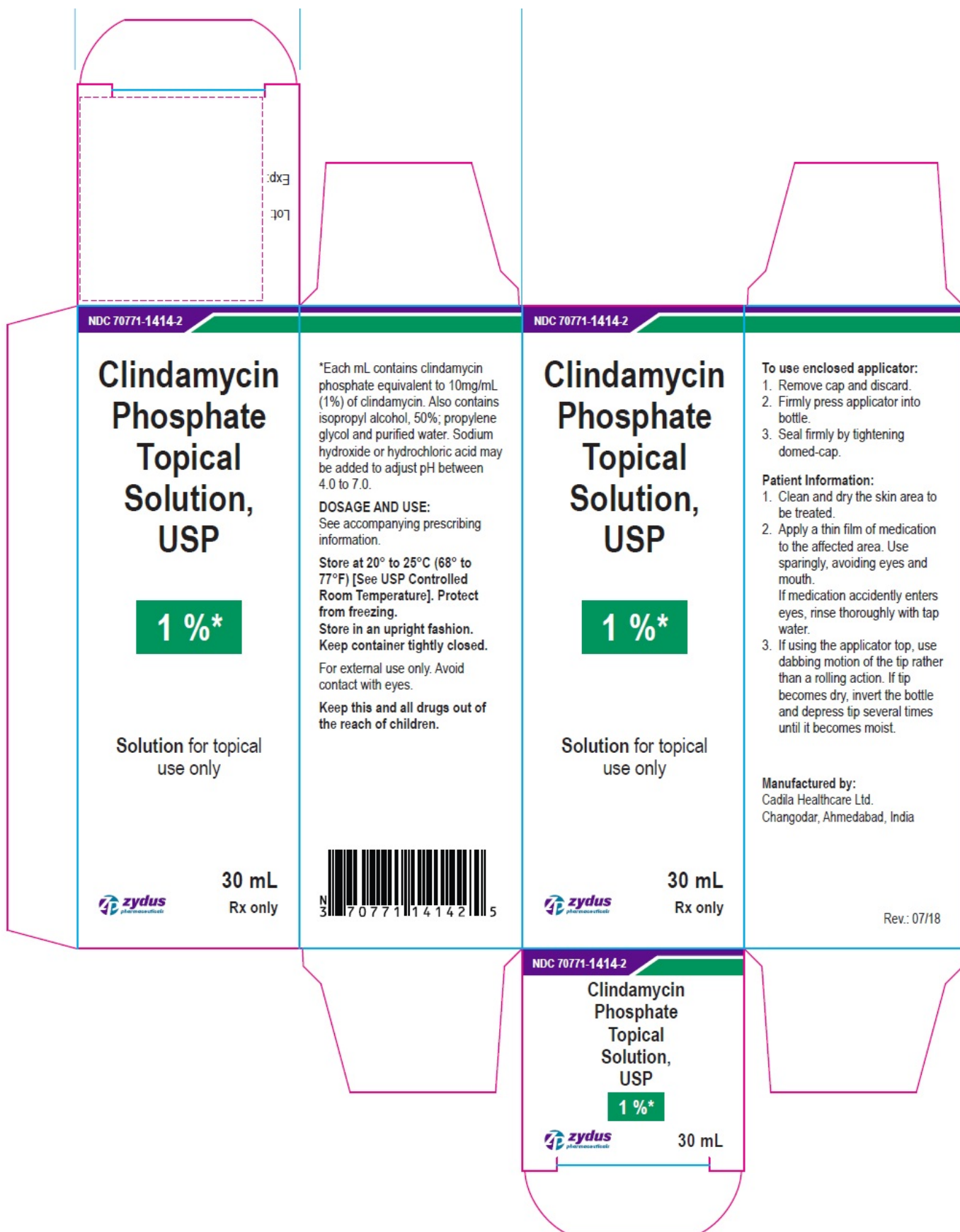
Keep this and all drugs out of the reach of children.

Patient Information:

1. Clean and dry the skin area to be treated.
2. Apply a thin film of medication to the affected area. Use sparingly, avoiding eyes and mouth. If medication accidentally enters eyes, rinse thoroughly with tap water.
3. If using the applicator top, use dabbing motion of the tip rather than a rolling action. If tip becomes dry, invert the bottle and depress tip several times until it becomes moist.

Manufactured by:
Cadila Healthcare Ltd.
Changodar, Ahmedabad, India

Rev 07/18



CLINDAMYCIN PHOSPHATE

clindamycin phosphate solution

Product Information				
Product Type		HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:70771-1414
Route of Administration		TOPICAL		
Active Ingredient/Active Moiety				
Ingredient Name			Basis of Strength	Strength
CLINDAMYCIN PHOSPHATE (UNII: EH6D7113I8) (CLINDAMYCIN - UNII:3U02EL437C)			CLINDAMYCIN PHOSPHATE	10 mg in 1 mL
Inactive Ingredients				
Ingredient Name				Strength
HYDROCHLORIC ACID (UNII: QTT17582CB)				
ISOPROPYL ALCOHOL (UNII: ND2M416302)				
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)				
SODIUM HYDROXIDE (UNII: 55X04QC32I)				
WATER (UNII: 059QF0K00R)				
Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:70771-1414-2	1 in 1 CARTON	01/03/2019	
1		30 mL in 1 BOTTLE; Type 0: Not a Combination Product		
2	NDC:70771-1414-3	1 in 1 CARTON	01/03/2019	
2		60 mL in 1 BOTTLE; Type 0: Not a Combination Product		
Marketing Information				
Marketing Category		Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA		ANDA208767	01/03/2019	

Labeler - Cadila Healthcare Limited (918596198)

Registrant - Cadila Healthcare Limited (650650802)

Establishment

Name	Address	ID/FEI	Business Operations
Cadila Healthcare Limited		650650802	ANALYSIS(70 771-1414) , MANUFACTURE(70 771-1414)